

### **REMARKS/ARGUMENTS**

This case has been carefully reviewed and analyzed in view of the Official Action dated 7 December 2005. Responsive to the objections and rejections made in the Official Action, Claim 3 has been canceled and Claims 1, 2, 4, 8 and 9 have been amended for further prosecution with the other pending Claims. It is believed that with such amendment of Claims, there is a further clarification of the pending Claims' recitations.

In the Office Action, the Examiner objected to the Specification as lacking antecedent basis for Claim 7's recitation of the wire being made of metallic or non-metallic material with a predetermined stiffness. In response to this objection, the Specification has been amended and now provides proper antecedent basis for Claim 7's recitation of the wire being made of metallic or non-metallic material with a predetermined stiffness.

In the Office Action, the Examiner objected to Claims 1 and 7-9 due to informalities therein. In response to this objection, the appropriate Claims have been amended to correct the informalities found therein.

In the Office Action, the Examiner rejected Claims 1-3, 7, 8 and 12 under 35 U.S.C. § 102(b) as being anticipated by Wallace (U.S. Patent 2,649,092). Prior to a discussion of the prior art relied upon by the Examiner in the Office Action, it is believed that it would be beneficial to briefly review the subject Application as now defined by amendment independent Claims 1, 8 and 9. Among its

combination of features, Applicant's self-retaining urinary drainage catheter system is one in which the catheter is of "sufficient stiffness to be reversibly insertable in a human being without using a stylet". As Applicant has detailed in the Specification, the use of a stylet to introduce the catheter into the urinary tract and bladder is dangerous, potentially traumatizing and can lead to perforation of the urethra wall, a most serious complication. Additionally, among its combination of features, Applicant's self-retaining urinary drainage catheter system recites the "plurality of drainage apertures being in direct fluid communication with said lumen" and "a wire control device positionally located external and displaced from said longitudinally extending flexible tube." The drainage apertures permit the draining of urine from the bladder without any residual urine being left over. Also as detailed in the Specification, the presence of residual urine promotes infection and is a further source of bladder irritation.

In contradistinction, the Wallace reference discloses a catheter that necessitates the use of a "stylet" to insert the catheter into a body passage. The Wallace reference makes this abundantly clear, and specifically states, "A stylet (not shown) is inserted in tubular member 12 and its forward end is brought to bear against the rearward end of plug 24. The stylet is moved forwardly with respect to the tubular member, causing portions 20 to be extended due to their flexibility, and the catheter and stylet are inserted in a body passage to the desired location, such as into the bladder. The stylet is then removed, allowing the parts

of the catheter to return to the position shown in Figure 1.” (column 3, lines 21-32) The Wallace reference goes on to further discuss the use of the stylet during removal of the catheter and specifically states, “the catheter may then be removed or, if desired, a stylet may be inserted in tubular member 12 and actuated to further protract forward end 14 with respect to the remainder of the tubular member before removal.”

Furthermore, Wallace discloses a wire control device that exists and is part of the lumen of the catheter. Whereas, Applicant teaches a wire control device that is external to the flexible tube. This feature in combination with the stiffness of the catheter allows such to be inserted into the bladder without a stylet.

Nowhere does the reference disclose or suggest, “... said catheter being of sufficient stiffness to be reversibly insertable in a human being without using a stylet ...” nor “... a wire control device positionally located external and displaced from said longitudinally extending flexible tube ...” as is defined in independent Claims 1 and 8. The Wallace reference, as detailed above, specifically necessitates the use of a stylet to insert its disclosed catheter. Applicant has detailed in the Specification the dangers associated with the use of a stylet during the insertion of a catheter into the bladder. Applicant’s device is one which removes the possibilities of those detailed dangers by teaching a catheter that has sufficient stiffness to be inserted into the bladder of a human being without the use of a stylet.

As the Wallace fails to disclose each and every element of the invention of the subject Patent Application, it cannot anticipate the invention as now claimed. Further, as the reference fails to suggest the combination of elements now claimed, it cannot make obvious that claimed invention. Additionally, Claims 2-7 are ultimately dependent upon now amended independent Claim 1 and are at least patentably distinct for the same reasons as independent Claim 1.

In the Office Action, the Examiner further rejected Claim 1 under 35 U.S.C. § 102(b) as being anticipated by Baskin, et al. (U.S. Patent 2,854,983). Baskin, et al. is directed to an inflatable catheter that has a forward end portion of the tubular member including a plurality of entrance openings 18 which establish communication between passage 14 and the exterior of the catheter. There is a second longitudinal passage 20 that is formed in the wall of the tubular member 12 that communicates with a flexible conduit 22 which is used to admit air through the conduit 22 and passage 20 thereto inflating the inflatable bag 24.

Nowhere does the Baskin, et al. reference disclose or suggest, "... said first configuration of flexible tube slit portions ... defining a plurality of drainage apertures ... said plurality of drainage apertures being in direct fluid communication with said lumen ...", as is now defined in amended independent Claim 1. Baskin, et al. specifically discloses that the "inflatable bag encircles the tubular member rearward of the openings of the [entrance] openings and is secured thereto in any suitable manner known to the art." Thus, by not providing a

plurality of drainage apertures at the flexible tube slit portions, the inflatable catheter disclosed by Baskin, et al. results in the retention and remainder of urine in the bladder. As detailed above, the presence of residual urine promotes infection and is a further source of bladder irritation. A careful examination of the Baskin, et al. reference shows that Baskin, et al. does not contemplate the use of drainage apertures that are in “direct fluid communication with said lumen”. The only openings contemplated by Baskin, et al. are the entrance openings 18 which are proximal to the inflatable bag area, specifically evidenced by Figures 1-6.

Therefore, as the Baskin, et al. reference fails to disclose or suggest, “... said first configuration of flexible tube slit portions ... defining a plurality of drainage apertures ... said plurality of drainage apertures being in direct fluid communication with said lumen ...”, as is shown in amended independent Claim 1, it is not believed to anticipate the invention of the subject Patent Application as now claimed. Further, as the reference fails to suggest the combination of elements as now claimed, it cannot make obvious that claimed invention.

In the Office Action, the Examiner rejected Claims 4-6 and 9-11 under 35 U.S.C. § 103(a) as being unpatentable over Baskin, et al. as applied to Claim 1, and further in view of Rosenberg (U.S. Patent 4,787,892). In setting forth this rejection, the Examiner acknowledged that Baskin, et al. fails to disclose a valve, but cited Rosenberg for teaching such and concluded that it would have been obvious to one of ordinary skill in the art to add the valve of Rosenberg to the

fluid inflation tube of the catheter of Baskin, et al. in order to provide a means of keeping the balloon inflated.

As newly-amended independent Claim 9 more clearly recites, Applicant's claimed self-retaining urinary drainage catheter system includes among its combination of features a plurality of drainage apertures that are in direct fluid communication with the lumen. The plurality of drainage apertures are defined by the first configuration of flexible tube slit portions.

The full combination of these and other features now more clearly recited by Applicant's pending Claims is nowhere disclosed by the cited references. As detailed above, the Baskin, et al. reference is deficient in disclosing a plurality of drainage apertures that are defined by the first configuration of flexible tube slit portions. Lacking this element, results in the catheter of Baskin, et al. to cause residual urine retention in the bladder thus leading to infection and bladder irritation.

The Rosenberg, reference much in the manner of the Baskin, et al. reference fails to disclose or suggest the plurality of drainage apertures that are in direct fluid communication with the lumen. Furthermore, Rosenberg discloses a catheter that necessitates the use of a hollow elongated stylet in order to facilitate insertion of the catheter. Neither the Baskin, et al., nor the Rosenberg reference disclose or suggest the concept of providing a plurality of drainage apertures that are defined by the first configuration of flexible tube slit portions to enhance

drainage of urine from the bladder thereby reducing the residual urine in the bladder.

Given the deficient teachings of the Baskin, et al. reference, the secondarily-cited Rosenberg reference is found to be quite ineffectual to the present patentability analysis. The secondary reference was cited for disclosing a valve but fails to sufficiently remedy the deficiencies of the Baskin, et al. reference.

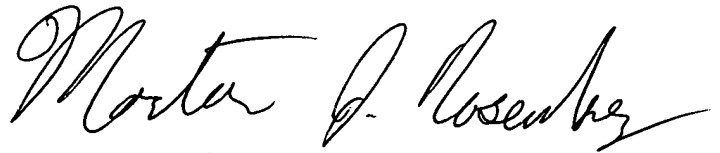
It is respectfully submitted, therefore, that the Baskin, et al. and Rosenberg references, even when considered together, fail to disclose the unique combination of elements now more clearly recited by Applicant's pending Claims for the purpose and objectives disclosed in the subject Patent Application. Additionally, Claims 4-6 are dependent upon amended independent Claim 1 which has been shown to be patentably distinct over the primarily-cited Baskin, et al. reference.

Although the Examiner asserts that the elements of the subject Patent Application are well-known, it is to be emphasized that it is the combination of elements, which Applicant teaches, that provides for a superior device over those in the prior art.

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It is now believed that the subject Patent Application has been placed in  
condition for allowance and such action is respectfully requested.

Respectfully submitted,  
For: ROSENBERG, KLEIN & LEE

A handwritten signature in black ink, appearing to read "Morton J. Rosenberg". The signature is fluid and cursive, with the first name "Morton" being more prominent.

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